Appendix V.

Senate Bill 6088
Laws and Rules
For the Prescription Drug Program

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CERTIFICATION OF ENROLLMENT

SENATE BILL 6088

58th Legislature
2003 1st Special Session
Passed by the Senate June 5, 2003
YEAS 43 NAYS 5

President of the Senate

Passed by the House June 5, 2003
YEAS 95 NAYS 2

Speaker of the House of Representatives

CERTIFICATE

I, Milton H. Doumit, Jr., Secretary of the Senate of the State of Washington, do hereby certify that the attached is SENATE BILL 6088 as passed by the Senate and the House of Representatives on the dates hereon set forth.

Secretary

Approved

Governor of the State of Washington

FILED

Appendix V. - Senate Bill 6088 Laws and Rules For the Prescription Drug Program

Secretary of State
State of Washington

SENATE BILL 6088

Passed Legislature - 2003 1st Special Session

State of Washington 58th Legislature 2003 1st Special Session

By Senators Deccio, Thibaudeau, Winsley, Swecker and Franklin

Read first time . Referred to .

AN ACT Relating to making prescription drugs more affordable to seniors, the disabled, and state health care programs; amending RCW 69.41.150 and 70.14.050; adding new sections to chapter 74.09 RCW; adding new sections to chapter 41.05 RCW; adding a new section to chapter 69.41 RCW; adding new sections to chapter 43.131 RCW; creating new sections; prescribing penalties; and declaring an emergency.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

{+ NEW SECTION. +} Sec. 1. The legislature finds that prescription drugs are an effective and important part of efforts to maintain and improve the health of Washington state residents. However, their increased cost and utilization is straining the resources of many state health care programs, and is particularly hard on low-income elderly people who lack insurance coverage for such drugs. Furthermore, inappropriate use of prescription drugs can result in unnecessary expenditures and lead to serious health consequences. It is therefore the intent of the legislature to support the establishment by the state of an evidence-based prescription drug program that identifies preferred drugs, develop programs to provide prescription drugs at an affordable price to those in need, and increase public awareness regarding their safe and cost-effective use.

{+ NEW SECTION. +} Sec. 2. A new section is added to chapter 74.09 RCW to read as follows:

(1) To the extent funds are appropriated specifically for this purpose, and subject to any conditions placed on appropriations made for this purpose, the department shall design a medicaid prescription drug assistance program.
Neither the benefits of, nor eligibility for, the program is considered to be an entitlement.

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(2) The department shall request any federal waiver necessary to implement this program. Consistent with federal waiver conditions, the department may charge enrollment fees, premiums, or point-of-service cost-sharing to program enrollees.

(3) Eligibility for this program is limited to persons:

(a) Who are eligible for medicare or age sixty-five and older;

(b) Whose family income does not exceed two hundred percent of the federal poverty level as adjusted for family size and determined annually by the federal department of health and human services;

(c) Who lack insurance that provides prescription drug coverage; and

(d) Who are not otherwise eligible under Title XIX of the federal social security act.

(4) The department shall use a cost-effective prescription drug benefit design. Consistent with federal waiver conditions, this benefit design may be different than the benefit design offered under the medical assistance program. The benefit design may include a deductible benefit that provides coverage when enrollees incur higher prescription drug costs as defined by the department. The department also may offer more than one benefit design.

(5) The department shall limit enrollment of persons who qualify for the program so as to prevent an overexpenditure of appropriations for this program or to assure necessary compliance with federal waiver budget neutrality requirements. The department may not reduce existing medical assistance program eligibility or benefits to assure compliance with federal waiver budget neutrality requirements.

(6) Premiums paid by medicaid enrollees not in the medicaid prescription drug assistance program may not be used to finance the medicaid prescription drug assistance program.

(7) This program will be terminated within twelve months after implementation of a prescription drug benefit under Title XVIII of the federal social security act.

(8) The department shall provide recommendations to the appropriate committees of the senate and house of representatives by November 15, 2003, on financing options available to support the medicaid prescription drug assistance program. In recommending financing options, the department shall explore every opportunity to maximize federal funding to support the program.

{+ NEW SECTION. +} Sec. 3. A new section is added to chapter 41.05 RCW to read as follows:

(1) In negotiating price discounts with prescription drug manufacturers for state purchased health care programs, the health care authority shall also negotiate such discounts for any Washington resident:

(a) Whose family income does not exceed three hundred percent of the federal poverty level as adjusted for family size and determined annually by the federal department of health and human services;

(b) Whose existing prescription drug need is not covered by insurance; and

(c) Who is: (i) At least fifty years old; or (ii) between the ages of nineteen and forty-nine and is otherwise eligible for benefits under Title II of the social security act, federal old age, survivors, and disability insurance benefits.

(2)(a) An attestation, which shall be submitted to the administrator, from an individual that the individual's family income does not exceed three hundred percent of the federal poverty level is sufficient to satisfy the eligibility requirement of subsection (1)(a) of this section.

(b) Any person willfully making a false statement in order to qualify for discounts under this section is guilty of a misdemeanor. Notice of such shall be included on the program enrollment form.

(3) The administrator shall charge participants in this program an annual enrollment fee sufficient to offset the cost of program administration.

(4) Any rebate or discount provided by a pharmaceutical manufacturer and made available to individuals under this section shall not be at the expense of retail pharmacies. This does not prohibit participating state agencies from using discounted pharmacy reimbursements for services or ingredients provided by the pharmacies.

{+ NEW SECTION. +} Sec. 4. A new section is added to chapter 41.05 RCW to read as follows:

The consolidated prescription drug purchasing account is created in the custody of the state treasurer. All fees collected under section 3(3) of this act shall be deposited into the account. Expenditures from the account may be used only for the purposes of section 3 of this act. Only the administrator or the administrator's designee may authorize expenditures from the account. The account is subject to allotment procedures under chapter 43.88 RCW, but an appropriation is not required for expenditures.

{+ NEW SECTION. +} Sec. 5. A new section is added to chapter 69.41 RCW to read as follows:

(1) Any pharmacist filling a prescription under a state purchased health care program as defined in RCW 41.05.011(2) shall substitute, where identified, a preferred drug for any nonpreferred drug in a given therapeutic class, unless the endorsing practitioner has indicated on the prescription that the nonpreferred drug must be dispensed as written, or the prescription is for a refill of an antipsychotic, antidepressant, chemotherapy, antiretroviral, or immunosuppressive drug, in which case the pharmacist shall dispense the prescribed nonpreferred drug.

(2) When a substitution is made under subsection (1) of this section, the dispensing pharmacist shall notify the prescribing practitioner of the specific drug and dose dispensed.

Sec. 6. RCW 69.41.150 and 1979 c 110 s 5 are each amended to read as follows:

(1) A practitioner who authorizes a prescribed drug shall not be liable for any side effects or adverse reactions caused by the manner or method by which a substituted drug product is selected or dispensed.

(2) A pharmacist who substitutes an equivalent drug product pursuant to RCW 69.41.100 through 69.41.180 as now or hereafter amended assumes no greater liability for selecting the dispensed drug product than would be incurred in filling a prescription for a drug product prescribed by its established name.

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{+ (3) A pharmacist who substitutes a preferred drug for a nonpreferred drug pursuant to section 5 of this act assumes no greater liability for substituting the preferred drug than would be incurred in filling a prescription for the preferred drug when prescribed by name. +}

{+ NEW SECTION. +} Sec. 7. A new section is added to chapter 41.05 RCW to read as follows:

(1) The administrator shall establish and advertise a pharmacy connection program through which health care providers and members of the public can obtain information about manufacturer-sponsored prescription drug assistance programs. The administrator shall ensure that the program has staff available who can assist persons in procuring free or discounted medications from manufacturer-sponsored prescription drug assistance programs by:

(a) Determining whether an assistance program is offered for the needed drug or drugs;

(b) Evaluating the likelihood of a person obtaining drugs from an assistance program under the guidelines formulated;

(c) Assisting persons with the application and enrollment in an assistance program;

(d) Coordinating and assisting physicians and others authorized to prescribe medications with communications, including applications, made on behalf of a person to a participating manufacturer to obtain approval of the person in an assistance program; and

(e) Working with participating manufacturers to simplify the system whereby eligible persons access drug assistance programs, including development of a single application form and uniform enrollment process.

(2) Notice regarding the pharmacy connection program shall initially target senior citizens, but the program shall be available to anyone, and shall include a toll-free telephone number, available during regular business hours, that may be used to obtain information.

(3) The administrator may apply for and accept grants or gifts and may enter into interagency agreements or contracts with other state agencies or private organizations to assist with the implementation of this program including, but not limited to, contracts, gifts, or grants from pharmaceutical manufacturers to assist with the direct costs of the program.

(4) The administrator shall notify pharmaceutical companies doing business in Washington of the pharmacy connection program. Any pharmaceutical company that does business in this state and that offers a pharmaceutical assistance program shall notify the administrator of the existence of the program, the drugs covered by the program, and all information necessary to apply for assistance under the program.

(5) For purposes of this section, "manufacturer-sponsored prescription drug assistance program" means a program offered by a pharmaceutical company through which the company provides a drug or drugs to eligible persons at no charge or at a reduced cost. The term does not include the provision of a drug as part of a clinical trial.

{+ NEW SECTION. +} Sec. 8. A new section is added to chapter 74.09 RCW to read as follows:

Each of the state's area agencies on aging shall implement a program intended to inform and train persons sixty-five years of age and older in the safe and appropriate use of prescription and

nonprescription medications. To further this purpose, the department shall award development grants averaging up to twenty-five thousand dollars to each of the agencies upon a showing that:

(1) The agency has the ability to effectively administer such a program, including an understanding of the relevant issues and appropriate outreach and follow-up;

(2) The agency can bring resources to the program in addition to those funded by the grant; and

(3) The program will be a collaborative effort between the agency and other health care programs and providers in the location to be served, including doctors, pharmacists, and long-term care providers.

Sec. 9. RCW 70.14.050 and 1986 c 303 s 10 are each amended to read as follows:

(1) Each agency (({- listed in RCW 70.14.010 -})) {+ administering a state purchased health care program as defined in RCW 41.05.011(2) +} shall (({- individually or -}))){+ , +} in cooperation with other agencies{+ , +} take any necessary actions to control costs without reducing the quality of care when reimbursing for or purchasing drugs. To accomplish this purpose, (({- each agency shall investigate the feasibility of and -})) {+ participating agencies +} may establish (({- a -})) {+ an evidence-based prescription +} drug (({- formulary designating which drugs may be paid for through their health care programs. For purposes of this section, a drug formulary means a list of drugs, either inclusive or exclusive, that defines which drugs are eligible for reimbursement by the agency -})) {+ program +}.

(2) In developing the {+ evidence-based prescription +} drug (({- formulary -})) {+ program +} authorized by this section, agencies:

(a) Shall prohibit reimbursement for drugs that are determined to be ineffective by the United States food and drug administration;

(b) Shall adopt rules in order to ensure that less expensive generic drugs will be substituted for brand name drugs in those instances where the quality of care is not diminished;

(c) Where possible, may authorize reimbursement for drugs only in economical quantities;

(d) May limit the prices paid for drugs by such means as {+ negotiated discounts from pharmaceutical manufacturers, +} central purchasing, volume contracting, or setting maximum prices to be paid;

(e) Shall consider the approval of drugs with lower abuse potential in substitution for drugs with significant abuse potential; (({- and -}))

(f) May take other necessary measures to control costs of drugs without reducing the quality of care {+ ; and

(g) Shall adopt rules governing practitioner endorsement and use of any list developed as part of the program authorized by this section +}.

(3) Agencies (({- may -})) {+ shall +} provide for reasonable exceptions{+ , consistent with section 5 of this act, +} to (({- the drug formulary required -})) {+ any list developed as part of the program authorized +} by this section.

(4) Agencies (({- may -})) {+ shall +} establish (({- medical advisory committees, or utilize committees already established, to assist -})) {+ an independent pharmacy and therapeutics

committee to evaluate the effectiveness of prescription drugs +} in the development of the (({- drug formulary required -})) {+ program authorized +} by this section.

{+ NEW SECTION. +} Sec. 10. A new section is added to chapter 41.05 RCW to read as follows:

The authority may adopt rules to implement this act.

{+ NEW SECTION. +} Sec. 11. By January 1, 2005, the administrator of the health care authority and the secretary of the department of social and health services shall submit to the governor and the legislature a progress report regarding the implementation of the programs created in this act.

{+ NEW SECTION. +} Sec. 12. A new section is added to chapter 43.131 RCW to read as follows:

The discount program under section 3 of this act shall be terminated June 30, 2010, as provided in section 13 of this act.

{+ NEW SECTION. +} Sec. 13. A new section is added to chapter 43.131 RCW to read as follows:

Section 3 of this act, as now existing or hereafter amended, is repealed effective June 30, 2011.

{+ NEW SECTION. +} Sec. 14. If any provision of this act or its application to any person or circumstance is held invalid, the remainder of the act or the application of the provision to other persons or circumstances is not affected.

{+ NEW SECTION. +} Sec. 15. If any part of this act is found to be in conflict with federal requirements that are a prescribed condition to the allocation of federal funds to the state, the conflicting part of this act is inoperative solely to the extent of the conflict and with respect to the agencies directly affected, and this finding does not affect the operation of the remainder of this act in its application to the agencies concerned.

Rules adopted under this act must meet federal requirements that are a necessary condition to the receipt of federal funds by the state.

{+ NEW SECTION. +} Sec. 16. This act is necessary for the immediate preservation of the public peace, health, or safety, or support of the state government and its existing public institutions, and takes effect immediately.

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Chapter 182-50 WAC

PRESCRIPTION DRUG PROGRAMS

NEW SECTION

WAC 182-50-001 Authority and purpose. RCW 41.05.021 (1)(a)(iii) and 70.14.050 authorize the administrator to establish an independent Washington state pharmacy and therapeutics committee within the health care authority to evaluate available evidence of the relative safety, efficacy and the effectiveness of prescription drugs within a class of prescription drugs, in the development of an evidence-based prescription drug program for participating state purchased health care programs. This section requires the administrator to adopt rules governing practitioner endorsement and use of any preferred drug list developed as part of the prescription drug program.

NEW SECTION

WAC 182-50-005 Definitions. When used in this chapter:

(1) "Appointing authority" shall mean the following persons acting jointly: The administrator of the health care authority, the secretary of the department of social and health services, and the director of the department of labor and industries.

(2) "Committee" means the independent Washington state pharmacy and therapeutics committee created by RCW 41.05.021 (1)(a)(iii) and 70.14.050. At the election of the department of social and health services, the committee may serve as the drug use review board provided for in WAC 388-530-1850.

(3) "Drug" means the term as it is defined in RCW 69.41.010 (9) and (12).

(4) "Endorsing practitioner" means a practitioner who has reviewed the preferred drug list and has notified the health care authority that he or she has agreed to allow therapeutic interchange of a preferred drug for any nonpreferred drug in a given therapeutic class.

(5) "Practitioner" means a health care provider, except a veterinarian, as defined at RCW 18.64.011(9).

(6) "Preferred drug" means a drug selected by the appointing authority for inclusion in the preferred drug list used by applicable state agencies for state purchased health care programs.

(7) "Preferred drug list" or "PDL" means the list of drugs selected by the appointing authority to be used by applicable state agencies as the basis for the purchase of drugs in state purchased health care programs.

(8) "Prescription" has the meaning set forth in RCW 18.64.011(8).

(9) "Refill" means the continuation of therapy with the same drug (including the renewal of a previous prescription or adjustments in dosage) when a prescription is for an antipsychotic, antidepressant, chemotherapy, antiretroviral, or immunosuppressive drug.

(10) "State purchased health care" has the meaning set forth in RCW 41.05.011(2).

(11) "Therapeutic alternatives" are drug products of different chemical structure within the same pharmacologic or therapeutic class and that are expected to have similar therapeutic effects and safety profiles when administered in therapeutically equivalent doses.

(12) "Therapeutic interchange" means to dispense, with the endorsing practitioner's authorization, a therapeutic alternative to the prescribed drug.

NEW SECTION

WAC 182-50-010 Purpose of the pharmacy and therapeutics committee. The purpose of the committee is to evaluate the available evidence of the relative safety, efficacy, and effectiveness of prescription drugs within a class of prescription drugs and make recommendations to the appointing authority for its deliberation in the development of the preferred drug list established in RCW 70.14.050.

NEW SECTION

WAC 182-50-015 Open Public Meetings Act and Administrative Procedure Act; exception as technical review committee. (1) Meetings of the pharmacy and therapeutics committee shall in all respects comply with the provisions of the Open Public Meetings Act, chapter 42.30 RCW, and shall be subject to the provisions of the Administrative Procedure Act, chapter 34.05 RCW, as applicable.

(2) The pharmacy and therapeutics committee shall constitute a technical review committee created to facilitate the development, acquisition, or implementation of a preferred drug list, for the purposes of state purchased health care under RCW 41.05.026, and as such may hold an executive session in accordance with chapter 42.30 RCW during any regular or special meeting to discuss information submitted in accordance with RCW 41.05.026 (1) through (5).

NEW SECTION

WAC 182-50-025 Membership and qualifications of pharmacy and therapeutics committee. (1) The committee shall consist of no fewer than ten members appointed by the appointing authority.

(2) The appointing authority has the sole right to appoint committee members and may terminate appointment of any member at any time during the term.

(3) The appointing authority will make appointments to the committee from a pool of interested applicants. Interested persons will be provided an opportunity to submit applications to the appointing authority.

(4) Members shall enter into an agreement with the health care authority at the time of their appointment to the committee and shall act in accordance with all of its terms and conditions. Failure to do so may result in termination of the appointment.

(5) The membership composition at all times shall be consistent with applicable federal requirements under the Federal Social Security Act, Title 19 § 1927 and the requirements of the department of social and health services medical assistance administration for its drug utilization review board. Therefore, pharmacists and physicians each shall represent at least thirty-one percent, but no more than fifty-one percent of committee membership respectively.

(6) Members must be actively practicing in their clinical area of expertise throughout the entire term of their appointments.

(7) Members must have knowledge and expertise in one or more of the following:

(a) Clinically appropriate prescribing of covered outpatient drugs;

(b) Clinically appropriate dispensing and monitoring of covered outpatient drugs;

(c) Drug use review;

(d) Medical quality assurance;

(e) Disease state management; or

(f) Evidence-based medicine.

(8) Members of the committee shall not be employed by a pharmaceutical manufacturer, a pharmacy benefits management company, or by any state agency administering state purchased health care programs during their term shall not have been so employed and for eighteen months prior to their appointment.

(9) A member shall not have a substantial financial conflict of interest including any interest in any pharmaceutical company, including the holding of stock options or the receipt of honoraria or consultant moneys. The appointing authority in its sole discretion may disqualify any potential member if it determines that a substantial conflict of interest exists.

(10) As part of the application process, prospective committee members shall complete a conflict of interest disclosure form, provided by the appointing authority, and after appointment, annually by July 1st of each year. Members must keep their disclosure statements current and provide updated information whenever circumstances change.

(11) Committee members must agree to keep all proprietary information confidential.

NEW SECTION

WAC 182-50-030 Period of appointment. (1) Members shall be appointed to a term of three years and shall serve until a successor is duly appointed. A member may be reappointed to one additional three-year term for a total of six years. One year after the end of a six-year term, a person is eligible for appointment to one additional three-year term.

(2) Committee members serve staggered three-year terms. Of the initial appointees, in order to provide for staggered terms, some members may be appointed initially for less than three years. If the initial appointment is for less than twenty-four months, that period of time shall not be counted toward the limitation of years of appointment described in subsection (1) of this section.

(3) Vacancies on the committee will be filled for the balance of the unexpired term from nominee lists for the appropriate committee category as provided under WAC 182-50-025.

(4) Members of the committee will be compensated for participation in the work of the committee in accordance with a personal services contract executed after appointment and prior to commencement of activities related to the work of the committee.

NEW SECTION

WAC 182-50-035 Duties. Committee members shall:

(1) Select a chair and a vice-chair from among the committee membership.

(2) Meet at least quarterly and may meet at other times at the discretion of the chair.

(3) Adopt a plan of operation that sets forth the policies and procedures established by the committee to develop an evidence-based prescription drug program as authorized by state law for approval by the appointing authority.

(4) Operate according to the plan of operation as approved by the appointing authority.

NEW SECTION

WAC 182-50-200 Endorsing practitioner therapeutic interchange program; effect of practitioner's endorsing status; dispense as written instructions. (1) When filling prescriptions for participating state purchased health care programs, pharmacists shall dispense a preferred drug in place of a drug not included in the preferred drug list in a given therapeutic class whenever pharmacists receive a prescription from an endorsing practitioner except:

(a) If the endorsing practitioner determines the nonpreferred drug is medically necessary by indicating "dispense as written" on the prescription; or

(b) If the prescription is a refill of an antipsychotic, antidepressant, chemotherapy, antiretroviral, or immunosuppressive drug.

(2) When a therapeutic interchange is made, the pharmacist shall notify the endorsing practitioner of the specific drug and dose dispensed.

(3) When a nonendorsing practitioner issues a prescription for a drug not included in the preferred drug list, the pharmacist shall dispense the prescribed drug in accordance with the requirements of RCW 69.41.100 through 69.41.180.